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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,020	09/29/2000	Thomas J. Gardella	0609.4820002/SRL/TBB	2982

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EXAMINER	
LAZAR WESLEY, ELIANE M	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/02/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/672,020	Gardella
Examiner	**Art Unit**
Eliane Lazar-Wesley	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☒ Claim(s) 1-41 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 8-12, drawn to polypeptides, classified in class 530, subclass 327.

II. Claims 3-12, 22-27, 40, drawn to polypeptides, classified in class 530 , subclassdepending on the species.

III. Claims 13, 15-21, drawn to nucleic acid encoding the polypeptide of claims 1-2, vectors, cells, classified in class 435, subclass 69.1 for example.

IV. Claim 14, drawn to nucleic acid encoding the polypeptides of claim 7 , classified in class 435, subclass 69.1

V. Claims 29-38, drawn to methods of treating decreases in bone mass, using the polypeptide of claim 1, classified in class 514, subclass 14.

VI. Claims 29-38, drawn to methods of treating decreases in bone mass, using the polypeptides of claims 3-7, 22-27, 40, classified in class 514, subclass depending on the species.

VII. Claim 39, drawn to a method of increasing cAMP with the polypeptide of claim 1.

VIII. Claim 41, drawn to a method of increasing inositol phosphate with the polypeptide of claim 1.

Claim 28 could not be restricted, as it is not clear from which claim it depends.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and II are drawn to entirely different peptide constructs having different required elements. They do not have a common structure, vary in length (as some consist of a peptide of 14 amino acids, like in claim 1, while others comprise at least 28 amino-acids, like SEQ ID No:29 for example).

Groups I and III , and Groups II and IV, differ in that they are drawn to entirely different products having different chemical structures and different biological functions and uses. While the polypeptides of Groups I and II may be made by expressing the nucleic acids of Groups III and IV, respectively, they may also be chemically synthesized.

Groups V and VI are independent and distinct, as the methods of treating decreases in bone mass use different reagents having different structures and compositions.

Group I is related to the inventions of Groups V , and Group II is related to the invention of Group VI as products and processes of use which can be shown to be distinct if the the products may be used in a materially different manner, which in this case is true, the products may be used to increase bone or to raise antibodies. Also, the methods may be practiced using distinct products.

Group I is not related to Group IV, and Group II is not related to Group III, as the products are independent and distinct structurally and functionally.

Group I is not related to Group VI, as the product of Group I is not made or used in the method of Group VI.

Group I is related to the methods of Groups VII and VIII as product and and processes of use which can be shown to be distinct if the the products may be used in a materially different manner, which in this case is true, the products may be used to increase bone or to raise antibodies. Also, the methods may be practiced using distinct products.

Groups II-IV are not related to the methods of Groups VII-VIII, as they the products of Groups II-IV cannot be made or used in the methods of Groups VII-VIII.

The methods of Groups V-VIII are independent and distinct, as they use different reagnets and different steps to reach different goals.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, different subject matter and that the search required is different, restriction for examination purposes as indicated is proper.

4. This application contains claims of group II directed to the following patentably distinct species of the claimed invention: SEQ ID No:2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, and the nucleic acids encoding them (claim 13 recites the nucleic acid encoding the polypeptide of claim 1, while claim 14 recites the nucleic acid encoding the polypeptides of claim 7).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

October 01, 2002

ELW

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600